USER REQUIREMENT SPECIFICATION

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USER REQUIREMENT SPECIFICATION

FOR

MOBILE PRODUCT AUTHENTICATION

SOLUTION

	PHARMA DEVILS
	PRODUCTION DEPARTMENT

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1.0 General Information:

Name of Equipment/Instrument/System/Model/Make	Mobile product authentication solution- Pharmasecure.
Brief Description about the configuration of Equipment/Instrument/System	Mobile product authentication solution- Pharmasecure. provided anti-counterfeiting software with 1.Domino Inkjet printer, Model No- A200 +Duo 2. PC (Pentium 4,1GB RAM, HDD 50 GB, Window XP.
Quantity Required	04 Nos Printers. 03 Nos PC's in integration with pharmasecure provided anti-counterfeiting software.
Purpose of the equipment (Specific application)	Pharmasecure code will be printed on every strip/blister of indicated drugs during packing. Customers can verify the authenticity of this product by sending the code through SMS to pharmasecure's gateway number. The code gets verified in the secure system and the customer gets reply SMS on verification status. For anti-counterfeiting measures for …………..products.

S.No.	Parameters	Requirements Specification
2.0	**User Requirements**	
2.1	**Material of construction of components/ accessories**	Ink jet Printer with PC
2.2	**Specification of equipment/instrument/ system at the installation site** ➢ Width ➢ Length ➢ Diameter	Vendor has to confirm the Dimensions.
2.3	**Description of Accessories** ➢ List of Accessories ➢ Dimensions	Vendor has to confirm the accessories. Vendor has to confirm the dimensions.
2.4	**Location Suitability** ➢ Installation Space ➢ Operational Space	Length (L) X Width (W) X Height (H) = 5.00 m X 5.31 m X 4.70 m

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S.No.	Parameters	Requirements Specification
2.5	**Details of utilities required**	
	➢ Air, Water, Nitrogen, Hydrogen etc.	NA
	➢ Compressed air, steam	NA
	➢ Electrical supply	220VAC / 50HZ,
	➢ LAN (Local Area Network connection)	Yes
	➢ Spike guards	Yes
	➢ UPS back up system	Yes
	➢ Air conditioning / HVAC	HVAC
	➢ Air grade of specific class	As per class maintained in the room in which system to be installed.
2.6	**Environmental condition at installation site**	
	➢ Temperature	25°c±2°c
	➢ Humidity	40 ±10%
	➢ LUX level at working place	NLT 300 LUX
	➢ Noise level in decibels	NMT 80 DB
2.7	**Level of Automation**	
	➢ Fully Automatic (PLC based etc.)	Fully automatic
	➢ Semi Automatic	NA
	➢ Manual	NA
2.8	**Capacity and use**	
	➢ Max. Operating capacity	Vendor has to conform the maximum operating and output capacity.
	➢ Output capacity	
2.9	**Safety**	
	➢ Personnel safety	In the event of power failure the system shall protect the personnel, equipment & product. No person shall be allowed to work on the machine unless the person has been fully trained.
	➢ Environmental hazard if any	NA

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S.No.	Parameters	Requirements Specification
2.10	**Speed** ➢ RPM ➢ Operational speed	NA Vendor has to conform the minimum and maximum operational speed.
2.11	**Nature of products to be handled**	Mobile product authentication solution to be used for printing of anti-counterfeiting codes on to strips/blisters as per requirement.
2.12	**Cleaning process parameters to be controlled** ➢ Clean in Place ➢ Manual Cleaning ➢ Water, Detergents, Solvents ➢ Cleaning procedure	NA Manual cleaning using lint free cloth. Vendor has to provide the cleaning procedure. Vendor has to provide the cleaning procedure.
2.13	**Critical process parameters to be controlled** ➢ Critical process parameters ➢ Control procedure	All parameters shall be measured, & monitored by system. 03 Level of password with authorization.
2.14	**Power failure and recovery** ➢ Probability ➢ Recovery procedure	In the event of power failure the system shall protect the personnel, equipment & product. The equipment shall not restart when electricity restored.
2.15	**Emergency stop** ➢ Provision for emergency stop	Yes
2.16	**Alarm warning** ➢ Indication of abnormality in operation	All the required indications shall be incorporated in the system.

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S.No.	Parameters	Requirements Specification
2.17	**Data security** ➢ Data storage ➢ Data integrity ➢ Data retrieval	PC 320 GB HDD Computer to be protected with different level of password with authorization. PC 320 GBHDD
2.18	**Constraints** ➢ Timelines ➢ Delivery	To be delivered at the following site of ULL, within 02 weeks from the date of approved Purchase Order. …………………
2.19	**Maintenance** ➢ Procedure ➢ Frequency	Vendor has to provide the procedure for maintenance. Vendor has to provide the frequency for maintenance
2.20	**Computer Configuration** ➢ Details of configuration through computer software	Should be compliance to USFDA 21 CFR part –11. Dual core processor/1GB RAM / 320 GB HDD / 18.5" TFT with accessories and startup consumables. As per vendor recommendations.
2.21	**Computer Hardware & Software Requirement** ➢ Hard disk storage capacity ➢ Compatible software with specific version ➢ 21 CFR part 11 compliant software	320 GB HDD Windows XP SP3 (OEM Pack) or as per vendor recommendations. Yes
2.22	**User License Requirement** ➢ Availability of sufficient licenses for used dept.	Sufficient licenses shall be available with user dept.

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S.No.	Parameters	Requirements Specification
2.23	**Commissioning and Documentation** ➢ Availability of the Engineer/s at the time of commissioning ➢ Availability of IQ, OQ, PQ protocols at the time of commissioning	DQ/IQ/OQ to be completed by the supplier (as per ULL Protocol) along with ULL representatives. ➢ Test certificate for major bought outs. ➢ Factory – In house test certificate. ➢ Instruction, operation and maintenance manual. ➢ As built drawings. ➢ Equipment electrical drawings. ➢ Mechanical drawing. ➢ Electrical wiring diagram. ➢ P & I diagram. All the test and calibration certificates shall be collected from vendor and it shall be traceable to National Standards.
3.0	**Training** ➢ Consent for training as and when required to user dept.	Training shall be given by the vendor.
4.0	**Reference documents** ➢ Operating manual ➢ Technical manual ➢ Trouble shooting manual ➢ Test certificates ➢ Calibration certificates	Required Required Required Required Required Supplier shall provide all the reference documents along with list of respective change parts & spares to be specified.

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5.0 ABBREVATIONS

Acronym	Definition
NA	Not Applicable
PC	Personal Computer
HDD	Hard Disk
NMT	Not More Than
VAC	Voltage AC
UPS	Uninterrupted Power Supply
DB	Decibel
IQ	Installation Qualification
DQ	Design Qualification
OQ	Operation Qualification
PQ	Performance Qualification

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This document has been prepared by User department, reviewed by Engineering and safety, approved by Quality Assurance, Unit Head and authorized by Functional Head. This document shall be sent to supplier / vendor for his acceptance.

APPROVALS

PREPARED BY: _____   DATE: _____
                    (USER DEPARTMENT)

REVIEWED BY: _____   DATE: _____
                    (ENGINEERING / SAFETY)

APPROVED BY: _____   DATE: _____
                    (QUALITY ASSURANCE)

APPROVED BY: _____   DATE: _____
                    (UNIT HEAD)

AUTHORIZED BY: _____   DATE: _____
                    (FUNCTIONAL HEAD {CORPORATE})

_____

ACCEPTED BY: _____   DATE: _____
                    (NAME, STAMP & SIGNATURE OF
                        SUPPLIER / VENDOR)